

K071593

SECTION F: 510(k) Summary

OCT 15 2007

510(k) SUMMARY

This summary of safety and effectiveness information is submitted in compliance with 21CFR807.92.

1. **Application Date:**
September 25, 2007
2. **Applicant Information:**
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

Contact Person: Margo Enright
Phone Number: 317-870-5610 x1064
FAX Number: 317-870-5608
e-mail: menright@cardiochek.com
3. **Trade Name:**
PTS PANELS CHOL+HDL Panel Test Strips
4. **Classification Names:**
Cholesterol (total) test system and Lipoprotein (high density lipoprotein) test system.
Panel: Clinical Chemistry 75
Product Codes: CHH, LBR
5. **Establishment Registration Number:**
1836135
6. **Facility Address:**
7736 Zionsville Road
Indianapolis, IN 46268
7. **Device Classification:**
Class 1 (Regulations: 21CFR 862.1175 and 862.1475)
8. **Intended Use:**
PTS PANELS CHOL+HDL Panel Test Strips are intended to be used by medical professionals and individuals in the home to measure cholesterol and high density lipoprotein cholesterol in whole blood. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various liver and renal diseases.
9. **Reason for 510(k):**
Device Modification

10. **Predicate Device Information**

The predicate devices for determination of substantial equivalence are:

Name: PTS PANELS Cholesterol Test Strips

PTS PANELS HDL Cholesterol Test Strips

Device Company: Polymer Technology Systems, Inc.

510(k) Numbers:

Cholesterol: K981493, K990688

HDL Cholesterol: K060617

Similarities and Differences between modified device (PTS PANELS CHOL+HDL Panel Test Strips) and the Predicate Device (unmodified- PTS PANELS Cholesterol and PTS PANELS HDL Cholesterol Test Strips)

Similarities Between Predicate and Modified Device

Item	Predicate	Modified Device
Intended Use	Intended to measure cholesterol and HDL cholesterol	Same
Technology	Dry chemistry test strip for use with PTS reflectance photometer.	Same
Product Storage	Store with vial tightly capped in a cool dry place at room temperature of 68-86°F.	Same
Specimen	Whole blood from fingerstick or venous blood collected in an EDTA or heparin tube.	Same
Chemistry Methods	Cholesterol: Colorimetric enzymatic (cholesterol esterase/oxidase) trinder method for cholesterol. HDL: Colorimetric enzymatic (cholesterol esterase/oxidase) trinder method for cholesterol. Dextran Sulfate fractionation.	Same
Calibration Curve	Resides on a read-only memory (EEPROM) chip packaged with the test strips.	Same

Differences Between Predicate and Modified Device

Item	Predicates	Modified Device
Number of test strips to obtain results	Two	One test strip containing two tests.
Time to obtain results	About one minute for each test result.	About two minutes.

11. **Compliance with Special Controls**

Does not apply.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Polymer Technology Systems, Inc.
c/o Ms. Margo Enright
Manager of Clinical Affairs
7736 Zionsville Road
Indianapolis, IN 46268

OCT 15 2007

Re: k071593
Trade/Device Name: PTS Panel CHOL+HDL Panel Test Strips
Regulation Number: 21 CFR §862.1175
Regulation Name: Cholesterol (total) test system.
Regulatory Class: Class I
Product Code: CHH, LBR
Dated: September 25, 2007
Received: September 27, 2007

Dear Ms. Enright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071593

Device Name: PTS PANELS CHOL+HDL Panel Test Strips

PTS PANELS CHOL+HDL Panel Test Strips are intended to be used by medical professionals and individuals in the home to measure cholesterol and high density lipoprotein cholesterol in whole blood. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various liver and renal diseases.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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